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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,231

08/31/2006

Ulrike Schulz

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EXAMINER

LEA, CHRISTOPHER RAYMOND

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

01/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/574,231	Applicant(s) SCHULZ ET AL.	
	Examiner Christopher R. Lea	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/30/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application is a 371 (national stage application) of PCT/EP05/051068.

Claims 10-33 are pending. Claims 10-33 are under examination.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on November 30, 2006, was filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-24, 29, & 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "... (a) at least one of an antiperspirant active ingredient and a deodorant active ingredient..." It is unclear whether the active is chosen between an

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antiperspirant or a deodorant, or whether the formulation contains both an antiperspirant and a deodorant. For purposes of examination, the examiner has interpreted the active to be at least one of an antiperspirant active ingredient or a deodorant active ingredient. It would be remedial to amend the claim as “...(a) at least one active ingredient selected from the group consisting of antiperspirant active ingredients and deodorant active ingredients...” or as “...(a) at least one active ingredient which is an antiperspirant active ingredient or a deodorant active ingredient...” to clarify the metes and bounds of the claim. Since claims 11-24 & 33 ultimately depend from claim 10, they have been rejected under 35 U.S.C. 112 second paragraph as well.

Claims 14 & 29 recite “...wherein (a) comprises at least one of aluminum chlorohydrate and an aluminum zirconium salt...” It is unclear whether the aluminum salt is chosen between aluminum chlorohydrate or an aluminum zirconium salt, or whether the formulation contains both aluminum chlorohydrate and an aluminum zirconium salt. For purposes of examination, the examiner has interpreted the active to be at least one of an aluminum chlorohydrate or an aluminum zirconium salt. It would be remedial to amend the claim, and the examiner suggests the following as possibilities “... wherein (a) comprises an aluminum salt selected from the group consisting of aluminum chlorohydrate, aluminum zirconium salts, and mixtures thereof ...” or “...wherein the aluminum salt is aluminum chlorohydrate, aluminum zirconium salt, or a mixture thereof...” It is noted that claims 14 and 29 do not utilize Markush group language. Thus, the position that these claims are indefinite is reasonable, for the aforementioned reasons.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 10, 12-24, & 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubino (US Patent 3,991,176).

Claims 10, 12-14: Rubino discloses a formulation (for use as antiperspirant) that comprises an antiperspirant active ingredient (Chlorhydrol, i.e. aluminum chlorohydrate), an α -hydroxycarboxylic acid (citric acid) and water (example IX, column 10, lines 1-18).

Claims 15-17: Rubino discloses a formulation where the ratio by weight of antiperspirant active ingredients to α -hydroxycarboxylic acid is approximately 7:1 (example IX, column 10, lines 1-18).

Claims 18-20: Rubino discloses a formulation (after drying and reconstitution) that has approximately 17% antiperspirant active agent (example IX, column 10, lines 1-18).

Claims 21 & 22: Rubino discloses a formulation (after drying and reconstitution) that has approximately 2.5% α -hydroxycarboxylic acid (example IX, column 10, lines 1-18).

Claim 23, 24, & 33: As to the claimed presence of a defined yield point, suitability for application to the human skin, transparency, and gel structure, where the

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claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed presence of a defined yield point, suitability for application to the human skin, transparency and gel structure since it is identical to the claimed composition (See MPEP § 2112.01).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 10, 11, & 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubino (US Patent 3,991,176) in view of Gross (US Patent 7,189,406).

Applicant claims

Applicant claims a cosmetic or dermatological formulation which is transparent and comprises an antiperspirant, α -hydroxycarboxylic acid and water.

Determination of the scope and content of the prior art (MPEP 2141.01)

Rubino teaches, as a whole, aluminum/zirconium antiperspirant compositions that contain α -hydroxycarboxylic acids.

Since claim 11 depends from claim 10, rejection of claim 10 under 35 USC 103 is also appropriate. Detailed discussion of the rejection of claim 10 by the teachings/disclosure of Rubino appears above.

Claims 25 & 29: Rubino teaches a formulation (for use as antiperspirant) that comprises an antiperspirant active ingredient (Chlorhydrol, aluminum chlorohydrate), an α -hydroxycarboxylic acid (citric acid) and water (example IX, column 10, lines 1-18). Absent evidence to the contrary, the prior art composition must possess the claimed transparency since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claims 26 & 27: Rubino teaches a formulation (after drying and reconstitution) that has approximately 17% antiperspirant active agent and approximately 2.5% α -hydroxycarboxylic acid (example IX, column 10, lines 1-18).

Claim 28: Rubino teaches a formulation where the ratio by weight of antiperspirant active ingredients to α -hydroxycarboxylic acid is approximately 7:1 (example IX, column 10, lines 1-18).

Claim 30: Rubino teaches a formulation (for use as antiperspirant) that comprises an antiperspirant active ingredient (Chlorhydrol, aluminum chlorohydrate), an α -hydroxycarboxylic acid (citric acid) and water (example IX, column 10, lines 1-18). Rubino teaches a formulation (after drying and reconstitution) that has approximately 17% antiperspirant active agent and approximately 2.5% α -hydroxycarboxylic acid (example IX, column 10, lines 1-18). Absent evidence to the contrary, the prior art

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composition must possess the claimed transparency since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claim 31: Rubino teaches a formulation where the ratio by weight of antiperspirant active ingredients to α -hydroxycarboxylic acid is approximately 7:1 (example IX, column 10, lines 1-18).

Claim 32: As to the claimed presence of a defined yield point, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed presence of a defined yield point since it is substantially identical to the claimed composition (See MPEP § 2112.01).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the teachings of Rubino and the instant claims is that Rubino does not use mandelic acid as the α -hydroxycarboxylic acid. This deficiency in Rubino is cured by the teachings of Gross.

Gross teaches, as a whole, skin treatment compositions.

Gross teaches mandelic acid is a preferred α -hydroxycarboxylic acid for stimulating skin-renewal (column 3, lines 56-67).

**Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize mandelic acid with its skin-renewing effects as taught by Gross as the α -hydroxycarboxylic acid in the antiperspirant formulations taught by Rubino and produce the instant invention. The skilled artisan would have been motivated to use mandelic acid because Gross teaches mandelic acid in a list of functionally equivalent α -hydroxycarboxylic acids with property of stimulating skin-renewal. Therefore the skilled artisan would have recognized that mandelic acid is both suitable for use in the topically applied antiperspirant of Rubino and equivalent to the α -hydroxycarboxylic acids already known to be employable in the Rubino invention.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in employing mandelic acid in the antiperspirant formulation of Rubino and producing the claimed invention, because mandelic acid is art recognized as being functionally equivalent with citric acid and other known alpha-hydroxy acids. Therefore, the invention as a whole would have

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been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 10-23, 25, 27, 30, & 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-27, 35, 38, 40, & 43 of copending Application No. 10/574,219 (the '219 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '219 application are species of the instant claims differing only in the claims of the '219 application more narrowly defining the

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antiperspirant ingredient. Since the claims of the '219 application are in a species relation to the instant claims, the instant claims are anticipated by the claims of the '219 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 10-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 17, 25-36, & 38 of copending Application No. 10/574,230 (the '230 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '230 application are species of the instant claims differing only in the claims of the '230 application more narrowly defining the form of the formulation as a microemulsion. Since the claims of the '230 application are in a species relation to the instant claims, the instant claims are anticipated by the claims of the '230 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 10-13, 15, 16, 19,21, 23, 25, & 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 43, 51-53, 56-59, 64, 75, & 81 of copending Application No. 11/586,585 (the '585 application). Although the conflicting claims are not identical, they are not patentably

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distinct from each other because the claims of the '585 application are species of the instant claims differing only in the addition of limitation concerning water content and the presence of particles in the formulation. Since the claims of the '585 application are in a species relation to the instant claims, the instant claims are anticipated by the claims of the '585 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 10-33 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616